

**TRADITIONAL 510(K)
SUMMARY OF SAFETY AND EFFECTIVENESS**

JUN 05 2014

Submitted by:
**Hectec GmbH
Ottostr. 16
84030 Landshut
GERMANY**

A. Date Prepared

May 20, 2014

B. Device Name and Classification

Trade Name:	mediCAD classic V3.0
Common Name	Software for Clinical Use
Classification Name:	Software for Clinical Use
Classification Panel:	Radiology
CFR Section:	21 CFR § 892.2050 (radiology.picture archiving and communications system) 21 CFR 888.4800 (orthopedic devices.template for clinical use)
Device Class:	Class II
Device Code:	LLZ (system, image processing, radiological)

Contact: Thomas Wengenmayer, quality management representative and regulatory
affairs representative HECTEC GmbH
Phone: +49 871 142370-0 FAX: +49 871 142370-9
Email: thomas.wengenmayer@hectec.eu

C. Device Intended Use

The mediCAD classic V3.0 is a medical stand-alone software, which allows professional orthopedics preoperative measurements of existing x-rays. The software is intended to read in diagnostic images (e.g. digitized x-rays) from PACS-systems or conventional medias and to dimension them. An integrated database of orthopedic implant geometries can be overlayed to aid surgeons in their planning of orthopedic surgeries. mediCAD classic 3.0 can hand over the digital plannings as DICOMs to PACS-systems. Federal law restricts this device to sale by or on the order of a health professional.

mediCAD will also support the proper workflow necessary to effectively compare pre and post-operative radiograph studies for a unique understanding of the patient's surgical outcome. Integrating this workflow with the orthopedic surgeons existing workflow and combining it with the data produced from the patient physical exam, provides a comprehensive data set for the continued prescription of a patient's relevant treatment and therapy.

The system is designed for the following medical specialties:

- Orthopedics
- Surgery and Traumatology

- Rheumatology
- Pediatric Orthopedics

MediCAD is designed for pre-operative planning for the following applications:

- Hip - Manual Planning
- Hip - Automatic Planning
- Hip - Biometry
- Hip - Coxometry
- Hip - Wear Measurement
- Hip - FAI
- Knee Prosthetic Planning
- Biometry Planning – takes into account patient motion and metrics
- Coxometry – tracking of known measurement values in pediatrics to determine surgical intervention
- Osteotomy – determines optimum osteotomy locations
- Osteotomy by Dror Paley
- Osteotomy (DualSide)
- Spine
- Foot
- Upper Extremities
- Biological Age Determination by Hand
- Trauma

D. Device Description

Concentrating within the specialty of joint replacement, mediCAD 3.0 will provide an orthopedic surgeon with the ability to produce pre-surgical plans and distribute those plans for intra operative guidelines. It will also support the proper workflow necessary to effectively compare pre and post-operative radiograph studies for a unique understanding of the patient's surgical outcome. Integrating this workflow with the orthopedic surgeons existing workflow and combining it with the data produced from the patient physical exam, mediCAD provides a comprehensive data set for the continued prescription of a patient's relevant treatment and therapy.

The proper choice of prosthesis implant, size and placement is critical to postoperative success and minimizing intra operative complications. Proper pre-surgical planning is key for identifying the correct choices and decisions an orthopedic surgeon makes.

The device has been designed and manufactured to conform to the following standards: Digital Imaging and Communications in Medicine (DICOM) V3.0, ISO/IEC 90003:2004 Software engineering — Guidelines for the application of ISO 9001:2000 to Computer software, ISO 14971:2007 Application of Risk Management of Medical Devices and ISO 13485:2003 Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes.

E. Substantial Equivalence Summary

The mediCAD 3.0 is substantially equivalent to AGFA's IMPAX Orthopedic Tool (FDA Clearance # K071972, Clearance Date 07/30/2007) for equal modules as the same software coding is used. Since the clearance date of AGFA's IMPAX

Orthopedic Tool, the modules Osteotomy dual side and hip FAI (femoro-acetabular-impingement) have been added.
For claiming substantial equivalence, TraumCad (K073714) has been used for further discussion and argumentation. Modules that are not components of the predicates have been subject to thorough testing. Performance has been proven through underlying medical literature and validation through health professionals.

	mediCAD classic 3.0	TraumCad 2.0	AGFA IOT
Hip - Manual Planning	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Hip - Automatic Planning	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Hip - Biometry	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Hip – Coxometry / Pediatrics	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Hip - Wear Measurement	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Hip - FAI	<input checked="" type="checkbox"/>		
Knee	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Osteotomy	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Osteotomy by Dror Paley	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>
Osteotomy (DualSide)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	
Intertrochanteric Osteotomy	<input checked="" type="checkbox"/>		
Spine	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Foot	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Upper Extremities	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Biological Age Determination by Hand	<input checked="" type="checkbox"/>		
TAYLOR SPATIAL FRAME (TSF)		<input checked="" type="checkbox"/>	
Trauma	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Table 1: Predicate Device Comparison

F. Comparison of Technological Differences:

MediCAD and its predicate devices are stand-alone software that can connect to PACS. Microsoft Windows is intended as operating system. Only scaling technologies differ. Nevertheless MediCAD's scaling method is as precise as the scaling methods of its predicate devices. Predicate devices also use an implant library in order to overlay them with digitized x-rays.

G. Testing

Verification testing have been executed by Hectec-employees to ensure that the requirement specifications have been fulfilled. Validation testing through professional medics in clinical environment confirm that the device meets performance, measurement and usability requirements. No clinical trials were performed in the development of the device.

The device has been designed and manufactured to conform to the following standards:

- ISO 14971:2012 Application of Risk Management to Medical Devices
- ISO 13485:2010 Medical Devices - Quality Management Systems - Requirements for Regulatory purposes

H. Conclusion

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 5, 2014

Hectec GmbH
% Mr. Thomas Wengenmayer
Quality Assurance Representative
Ottostr. 16
Landshut, Bavaria 84030
GERMANY

Re: K140434

Trade/Device Name: mediCAD Classic 3.0
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 19, 2014
Received: May 28, 2014

Dear Mr. Wengenmayer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140434

Device Name

mediCAD classic 3.0

Indications for Use (Describe)

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Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)